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CATHETER AND METHOD FOR GENERATING AXIAL TENSION ALONG CATHETER BODY

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Résumé:
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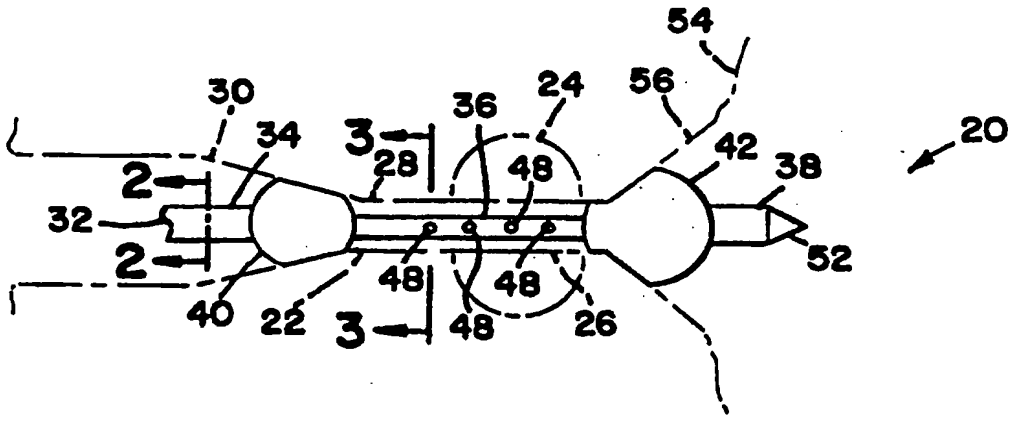

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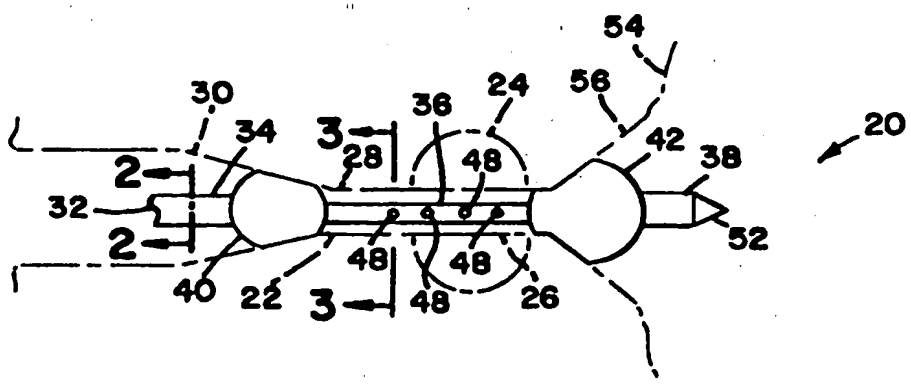

(57) Abstract

An apparatus for delivering fluid to a treatment area of a patient. The apparatus comprises a catheter (32) having first (34), second (36) and third (38) portions. The second portion (36) is more elastic than and positioned between the first (34) and third (38) positions. A proximal balloon (40) is operably connected to the first portion. A distal balloon (42) is operably connected to the third portion. The first portion has a first cross-sectional area, the second portion has a second cross-sectional area, and the third portion has a third cross-sectional area. The first and third cross-sectional areas are greater than the second cross-sectional area.

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CATHETER AND METHOD FOR GENERATING AXIAL TENSION ALONG CATHETER BODY

Technical Field

The present invention relates to catheters, and more specifically to a catheter that is configured to generate axial tension between multiple occlusion balloons.

Background

Many techniques exist for delivering drugs or other medicaments to body tissue. These techniques include oral administration; injection directly into body tissue, such as through an intramuscular injection; topical or transcutaneous administration where the drug is passively absorbed into, or caused to pass across, the skin or other surface tissue; and intravenous administration, which involves introducing a selected drug directly into the blood stream.

Except for topical or transcutaneous administration, the above drug delivery systems tend to be systemic. In other words, administration of the drug is delivered throughout the body by the blood stream. Transcutaneous drug delivery systems deliver a drug locally to a selected area, and are limited to external application of a drug through the patient's skin or other surface tissue. Thus, the above described drug delivery systems generally are not appropriate for the localized treatment of internal body tissue.

Although many medical situations are satisfactorily treated by the general systemic administration of a drug, there are many treatments that are facilitated and/or improved by the ability to deliver or administer a drug locally to a selected portion of internal body tissue, without appreciably affecting the surrounding tissue. One example is the prostate gland, which is subject to various diseases such as prostatitis, benign prostatic hyperplasia, and prostate cancer. The urethra allows relatively easy access to the prostate from outside the patient by means of a catheter.

The urethra includes the prostatic urethra, the membranous urethra, bulbous urethra, and the pendulous urethra. All of the major ducts of the prostate gland open on the surface of the prostatic urethra. These ducts extend into the prostate and branch into ductules (smaller ducts) and eventually end in acini (rounded sacs). The outside of the prostate gland is surrounded by a tough fibrous capsule that serves as a substantial physical barrier between the spongy prostatic tissue and the rest of the peritoneal environment. By using an appropriately designed catheter that is introduced through the urethra, it is possible to access the prostate gland via the prostatic ducts that extend deep into the gland.

There are devices configured to deliver fluids to the prostate gland via the prostatic urethra that have a delivery balloon made from a porous membrane. The delivery balloon is placed into the prostatic urethra and inflated with a fluid. The fluid is pressurized so that it is caused to pass through the porous or perforated membrane and transported into the prostatic ducts.

There are significant problems that result from delivering the fluid through this type of membranous balloon. For example, the transport of the fluid into the prostate gland is impeded and thus much less efficient.

One impediment is that the pressurized balloon expands and exerts a force against the walls of the prostatic urethra. This force compresses the prostatic tissue and causes the ducts to restrict and block the flow of the fluid into the prostate gland. As a result, the fluid typically does not distribute evenly throughout the ducts, nor throughout the prostate gland. Compression of the prostatic ducts also prevents or slows the flow of the fluid into the interior of the prostate gland.

Another impediment is the porous membrane through which the fluid must pass before it enters the prostatic ducts. Such an impediment slows the flow of the fluid and results in additional inefficiency. Slowing the flow of the fluid results in longer delivery times and most likely lower levels of drug in the prostate gland. Additionally, a longer administration period requires additional time from the caregiver. This expense is passed on to the patient, thereby increasing the cost of treatment.

Therefore, there is a need for a catheter that is capable of delivering drugs and diagnostic fluids to the prostate gland via the prostatic urethra and prostatic ducts, wherein the catheter does not compromise flow through the prostatic ducts by exerting pressure against the walls of the prostatic urethra.

There are also catheters that include multiple occlusion balloons. However, these catheters rely on only inflation pressure within the balloons in order to create a seal between the balloon and the wall of a passageway. Such devices have a significant problem because the balloon pressure alone is not always adequate to prevent a fluid from seeping between the balloon and the passageway wall during high pressure delivery. Therefore, there is also a need for a catheter that is capable of enhancing the sealing effect of occlusion balloons on a catheter.

Summary

The present invention is directed to an apparatus for delivering fluid to a treatment area of a patient. The apparatus comprises a catheter having first and second portions. The second portion is more elastic than the first portion. Distal and proximal balloons are operably connected to the catheter. The distal and proximal balloons are

positioned so that at least a part of the second portion of the catheter is located between the distal and proximal balloons.

Another embodiment of the present invention is a method of delivering an agent to the prostate gland of a patient having a urethra and bladder. The method utilizes a catheter having proximal and distal balloons and an intermediate portion between the proximal and distal balloons. The method comprises the steps of inserting the catheter through the urethra so that the distal balloon is positioned at the neck of the bladder; inflating the proximal and distal balloons; and providing axial tension along the intermediate portion of the catheter. The axial tension urges the proximal and distal balloons towards one another.

Description of the Drawings

Figure 1 is a partial view of the catheter of the present invention located in the drug delivery position within the male urethra and bladder.

Figure 2 is a cross section of the catheter shown in Figure 1 taken along line 2-2.

Figure 3 is a cross section of the catheter shown in Figure 1 taken along line 3-3.

Figure 4 is a partial view of the catheter illustrated in Figure 1 showing a pear-shaped distal occlusion balloon.

Figure 5 is a cross section of the pear-shaped distal occlusion balloon illustrated in Figure 4 taken along line 5-5.

Figure 6 is a partial view of the catheter illustrated in Figure 1 showing a distal occlusion balloon having a conical end portion.

Figure 7 is a partial view of the catheter illustrated in Figure 1 showing a cross-sectional view of a toroidal-shaped distal occlusion balloon.

Figure 8 is a partial cross section of the catheter illustrated in Figure 1 having an electrode.

Detailed Description

The present invention will be initially described in general terms. A preferred embodiment of the invention then will be described in detail with reference to the drawings, wherein like reference numerals represent like parts and assemblies throughout the several views. Reference to the preferred embodiment does not limit the scope of the invention, which is limited only by the scope of the claims attached hereto.

The present invention comprises a catheter with two balloons for isolating a target area for treatment. A portion of the catheter between the two balloons is elastic,

which enhances the sealing effect of the balloons. The catheter is capable of delivering fluid to the target area of the passageway that is isolated between the balloons. The present invention can be used to deliver fluid to the prostate gland and is advantageous in that the prostatic ducts remain substantially open, even when the balloons are inflated.

While the present invention is described in terms of a urinary catheter for treating a patient's prostate gland, one skilled in the art will realize that the present invention can be used with other types of catheters. For example, the present invention could be used with a cardio-vascular catheter; a catheter configured to treat a patient's windpipe; an endoscope, which is a form of catheter; or the like.

Referring now to Figure 1, which illustrates one possible embodiment of a catheter according to the present invention, generally shown as 20, for isolating a segment of the urethra 22 and treating a prostate gland 24. The urethra 22 includes the prostatic urethra 26, a membranous urethra 28, and a bulbous urethra 30. The prostatic urethra 26 is that portion of the urethra 22 that passes though the prostate gland 24.

The present invention includes a catheter body 32 having a proximal or first portion 34, an intermediate or second portion 36, and a distal or third portion 38. The proximal and distal portion 34 and 36 have a first outer diameter that is substantially uniform. A proximal occlusion balloon 40 and a distal occlusion balloon 42 are operably connected to catheter body 32 proximate oppositely disposed ends of intermediate portion 36. The distance between the proximal occlusion balloon 40 and the distal occlusion balloon 42 is approximately equal to the combined length of the average prostatic urethra 26 and the average membranous urethra 28.

Proximal and distal occlusion balloons 40 and 42 can be made from either elastic material or inelastic material. Examples of suitable elastic materials include latex, polyurethane, or silicon. Examples of suitable inelastic materials include polyethylene, polycarbonate, or PET.

Figure 2 illustrates a cross-section of the proximal portion 34 of catheter body 32. Figure 3 illustrates a cross-section of the intermediate portion 36 of the catheter body 32. As shown in these figures, catheter body 32 defines a delivery lumen 44 having a substantially uniform diameter and a first inflation lumen 46 having a substantially uniform diameter. Delivery ports 48 extend between the delivery lumen 44 and the surface of the catheter body 32 at a point between the distal and proximal occlusion balloons 40 and 42.

The first inflation lumen 46 is in fluid communication with distal occlusion balloon 42 via a first inflation port (not shown). A second inflation lumen 50 is in fluid communication with proximal occlusion balloon 40 via a second inflation port (not shown). A drainage lumen 51 extends through catheter body 32 and opens at

distal end 52. One skilled in the art will realize that the second inflation lumen 50 terminates proximal to the proximal occlusion balloon 40 and thus does not extend through the intermediate portion 36 of the catheter body 32.

As illustrated by Figures 2 and 3 a cross-section of proximal portion 34 of catheter body 32 has a greater area than the cross-section of intermediate portion 36 of catheter body 32. As a result, the intermediate portion 36 has more elasticity than proximal portion 34. The distal portion 38 of the catheter body 32 has a cross-sectional area similar to that of the proximal portion 34, which is represented in Figure 2.

One skilled in the art will realize that a part of the intermediate portion 36 can have a greater cross-sectional area as shown in Figure 2, so long as there is a segment of the intermediate portion 36 that has a smaller cross-sectional area so that elasticity is increased enough to permit the caregiver to generate axial tension between the proximal and distal occlusion balloons 40 and 42. One skilled in the art will further realize that the proximal and distal occlusion balloons 40 and 42 are preferably mounted on the catheter body 32 in a position that has the larger cross-sectional area shown in Figure 2. This positioning will ensure that the axial tension is concentrated between the proximal and distal occlusion balloons 40 and 42.

In an alternative embodiment, the catheter 20 can be made from two different materials having different elasticity. For example, the distal and proximal portions 34 and 38 of the catheter 20 might be formed from one material having a predetermined elasticity. The intermediate portion 36 then can be formed from a second material that has predetermined elasticity greater than the elasticity of the material that forms the proximal and distal portions 34 and 38 of the catheter body 32. The intermediate portion 36 can be spliced between the proximal and distal portions using a variety of manufacturing techniques that are well known in the art. In this alternative embodiment, the proximal, intermediate, and distal portions 34, 36, and 38 can have the same cross-sectional area.

The procedure for using catheter 20 is as follows. Catheter 20 is inserted into the urethra 22 using lubrication, sterile techniques, or any other technique that is commonly used to insert a Foley-type urological catheter. Catheter 20 is inserted into the urethra 22 until the distal occlusion balloon 42 enters the bladder 54 and is preferably inserted while there is urine within the bladder 54. Having urine within the bladder 54 is useful because the caregiver who inserts the catheter 20 will know that the distal occlusion balloon 42 has entered the bladder 54 when urine is observed in the drainage lumen 51 or when urine can be aspirated through the drainage lumen 51.

Once the distal occlusion balloon 42 is inserted within the bladder 54, fluid is injected through first inflation lumen 46 until the distal occlusion balloon 42 is inflated

to a diameter in the range of about 2 cm to about 4 cm. After distal occlusion balloon 42 is inflated, the caregiver pulls on the proximal portion 34 of the catheter body 32, which causes the intermediate portion 36 to expand, thereby generating axial tension. The proximal occlusion balloon 40 should be positioned in the bulbous urethra 30. The caregiver can then inflate the proximal occlusion balloon 40 and release the proximal portion 34 of the catheter body 32.

The elasticity of intermediate portion 36 causes axial tension that urges the distal and proximal occlusion balloons 40 and 42 to move toward one another. The axial tension seats the proximal occlusion balloon 40 against the narrowing wall of the bulbous urethra 30, which enhances its sealing effect. Additionally, the combination of pulling on the proximal portion 34 of the catheter body 32 and the resulting axial tension seats the distal occlusion balloon 42 at the bladder neck 56 and enhances its sealing effect.

When inflating the distal and proximal occlusion balloons 40 and 42, the caregiver can use a predetermined, fixed volume of fluid in order to prevent over inflation and bursting of the balloons 40 and 42. The fluid can be air, water, or saline, etc. However, the preferred fluid is sterile water.

When the catheter 20 in a delivery position, the distal occlusion balloon 42 is positioned so that it is primarily located in the bladder neck 56. However, a portion of distal occlusion balloon 42 may be located within the portion of the prostatic urethra 26 closest to the bladder neck 56. The reason is that substantially all of the prostatic ducts open in the proximal three quarters of the prostatic urethra 26. Consequently, positioning distal occlusion balloon 42 in this manner causes a minimal amount, if any, of the prostatic ducts to seal shut when the catheter 20 is in the delivery position.

Drugs or diagnostic fluids may be delivered to the prostate gland 24 after catheter 20 is in the delivery position and the proximal and distal occlusion balloons 40 and 42 are inflated. One skilled in the art will realize that a pressure gauge and syringe can be placed in fluid communication with delivery lumen 44 to deliver the drug or diagnostic fluid to the prostatic urethra 26. Any number of types of syringes may be used such as a standard syringe, an adjustable syringe, or a syringe pump. However, an adjustable syringe is preferably used. An adjustable syringe is one that has threads or some other type of self-locking mechanism.

Once delivered, the drug or diagnostic fluid is pressurized, thereby transporting it into the ducts, ductules, and acini. The pressure on the fluid may range between from about 0.1 psi to about 10 psi. However, the preferable pressure is between about 0.1 psi and about 6 psi. The most preferred range of pressure is between about 0.1 psi and about 5 psi. This pressure causes the fluid to fill the prostatic ducts, ductules, and acini.

Preferably, a constant pressure should be maintained over a period of time ranging from about 0.1 hours to about 4 hours. The preferred range of time is between about 0.1 hours to about 2 hours, and the most preferred range is between about 0.1 hours and about 0.5 hours. One skilled in the art will realize that the precise amount of time will vary depending on the drug or the diagnostic agent being employed.

Maintaining constant pressure over a period of time, rather than a simple administration of a fixed volume of drug solution, will more likely result in homogeneous prostatic tissue concentrations. If accurate drug dosing is not required, a fixed volume of solution can be simply administrated. An example of when a fixed volume of solution is appropriate is when a positive contrast agent is introduced into the prostate gland 24.

The preferable procedure for withdrawing catheter 20 from the urethra 22 depends on whether toxic or caustic agents were delivered. For nontoxic drugs and diagnostic fluids such as antibiotics, anti-inflammatories, and positive contrast agents, the pressure of the fluid is simply reduced to zero. The distal and proximal occlusion balloons 40 and 42 are then deflated, and catheter 20 is removed from the urethra 22.

If toxic or caustic agents were delivered, an alternative procedure for withdrawing catheter 20 is preferred. More specifically, a slight negative pressure is applied to the fluid in order to remove the excess drug or diagnostic agent from the urethra 22 after the administration period is complete. The urethra 22 may then be flushed with a saline solution. The saline solution is added and removed via the delivery lumen 44 in the same fashion the drug or diagnostic fluid was initially delivered to the prostatic urethra 26. After the saline solution is removed, distal and proximal occlusion balloons 40 and 42 are deflated and catheter 20 is removed.

One skilled in the art will realize that in an alternative embodiment, the distance between the proximal and distal occlusion balloons 40 and 42 can be about the same length as or slightly longer than the average prostatic urethra 26. In this alternative embodiment, the proximal occlusion balloon 40 will be located in the membranous urethra 28 when the catheter 20 is in the delivery position, so that the proximal occlusion balloon 40 will exert minimal pressure against the wall of the prostatic urethra 26. Thus, a minimal number of prostatic ducts will collapse when catheter 20 is in the drug delivery position.

When using this alternative embodiment, the caregiver should inflate the distal occlusion balloon 42 and then pull on the proximal portion 34 of the catheter body 32 which will generate axial tension along the intermediate portion 36. The caregiver can maintain the axial tension by taping or clamping the proximal portion 34 of the catheter body 32 to the patient's body. This action will ensure that the distal occlusion balloon 42 remains seated and sealed at the bladder neck 56. The caregiver should

then inflate the proximal occlusion balloon 40. The pressure of the inflation fluid will seal the proximal occlusion balloon 40 against the wall of the membranous urethra 28. This alternative embodiment is advantageous when delivering toxic or otherwise harmful drugs that could harm the patient if exposed to tissue other than the prostate gland 24.

If the proximal occlusion balloon 40 is to be located in the bulbous urethra 30 when the catheter 20 is in the delivery position, a possible range of distance between the proximal and distal occlusion balloons 40 and 42 is from about 3 cm to about 7 cm. If the proximal occlusion balloon 40 is to be located in the membranous urethra 28 when the catheter 20 is in the delivery position, a possible range of distance between the proximal and distal occlusion balloons 40 and 42 in this embodiment is from about 3 cm to about 6 cm. However, in all of the embodiments of the invention described herein, one skilled in the art will realize that the distance between the proximal and distal occlusion balloons 40 and 42 can vary depending on the length of the patient's urethra 22. Thus, in order to accommodate prostatic urethras 26 of different lengths and the delivery of different fluids, the caregiver may have several catheters 20 available, each having different distances between the proximal and distal occlusion balloons 40 and 42.

In yet another alternative embodiment, the catheter 20 may have a telescoping body (not shown) in which the proximal occlusion balloon 40 is attached to a tubular, outer portion and the distal occlusion balloon 42 is attached to an extendable, inner portion. A hemostatic-type adjustable seal can be used to secure the extendable portion relative to the tubular portion. Such a telescoping catheter body is described in commonly-assigned United States Patent 5,419,763, the disclosure of which is hereby incorporated by reference.

An advantage of a telescoping catheter body is that the distance between the proximal occlusion balloon 30 and the elongating balloon 28 can be adjusted to the length of the patient's urethra 15. Additionally, the relative position of the proximal occlusion balloon 30 can be adjusted so that it is positioned in either the membranous urethra 18 or the bulbous urethra 19 when the catheter 20 is in the delivery position.

Additionally, a telescoping catheter can be used in an alternative method of creating axial tension. Specifically, the caregiver can insert the catheter 20 through the patient's urethra so that the distal occlusion balloon 42 is located in the bladder 54 and the proximal occlusion balloon 40 is located in the bulbous urethra 30. The caregiver also inflates the proximal occlusion balloon 40 and the distal occlusion balloon 42.

After the proximal and distal occlusion balloons 40 and 42 are inflated, the caregiver can slide the tubular portion along the extendible portion, thereby causing proximal and distal occlusion balloons 40 and 42 to move toward one until the

proximal occlusion balloon 40 becomes seated against the wall of the bulbous urethra 30 and the distal occlusion balloon 42 becomes seated at the bladder neck 56.

Alternatively, the caregiver can initially position and then inflate the proximal occlusion balloon 40. Once the proximal occlusion balloon 40 is positioned, the caregiver can secure the tubular portion to the patient's body using tape or a clamping device. The distal occlusion balloon 42 is inflated. The caregiver then retracts the extendable portion until the distal occlusion balloon 42 is seated at the bladder neck 56 and there is a sufficient amount of axial tension between the proximal and distal occlusions 40 and 42. This alternative method of using a telescoping catheter is useful when the proximal occlusion balloon 40 is to be positioned in the membranous urethra 28 during delivery.

The distal occlusion balloon 42 can have a variety of configurations such as pear-shape, a balloon with a conical portion, a toroid shape, or other configurations. Figure 4 illustrates a first alternative embodiment in which a pear-shaped balloon 58, shown in an inflated state, serves as a unitary positioning balloon and distal occlusion balloon. The pear-shaped balloon 58 has a proximal portion 60 that is configured for isolating the prostatic urethra 26 and a distal portion 62 that is configured for locating the catheter 20 in the delivery position.

Figure 5 shows a cross-sectional view of the pear-shaped balloon 58 in a deflated state. When in the deflated state, the pear-shaped balloon 58 has a substantially uniform outer diameter. The thickness of the balloon wall at the proximal portion 60 is greater than the thickness of the wall at the distal portion 62. As a result, a chamber 64 defined by the pear-shaped balloon 58 has a smaller inner diameter at the proximal portion 60 than the distal portion 62.

When in the inflated state, the proximal portion 60 is sized to be placed into sealing engagement with the bladder neck 56. In an alternative embodiment, the proximal portion 60 can be sized to partially extend into the portion of the prostatic urethra 26 that is adjacent to the bladder neck 56. The distal portion 62 is wider than the proximal portion 60 and is configured to become seated at the bladder neck 56 and locate the catheter 20 in the delivery position when the caregiver initially pulls on the proximal portion 34 of the catheter body 32 as described above. Pear-shaped balloons are described in more detail in United States Patent 5,419,763, the disclosure of which was incorporated by reference above.

Figure 6 illustrates another alternative embodiment in which a distal occlusion balloon 65 has a proximal end 66 and a distal end 68. Proximal and distal ends 66 and 68 have a conical configuration. As a result, proximal end 66 fits snugly in the bladder neck 56 and creates a seal when distal occlusion balloon 65 is in an inflated state. This seal substantially isolates the prostatic urethra 26 from the bladder neck 56 and bladder

54. The use of balloons such as distal occlusion balloon 65 or pear-shaped balloon 58 are advantageous when delivering toxic or dangerous agents that may cause unwanted side effects or harm if exposed to tissue other than the prostate gland 24.

Figure 7 illustrates yet another alternative embodiment in which a toroid-shaped balloon 70 serves as the distal occlusion balloon. When in an inflated state, the toroid-shaped balloon 70 has a proximal end 72, that has an arcuate shape and is convex. In other words, the proximal end 72 bulges outward.

When the toroid-shaped balloon 70 is in the inflated state and properly positioned, the proximal end 72 creates a seal against the wall of the bladder 54. The bladder neck 56 remains in fluid communication with the prostatic urethra 26. The bladder 54 is substantially isolated from both the bladder neck 56 and the prostatic urethra 26. Using the toroid-shaped balloon 70 is advantageous when anesthetizing a patient before prostatic surgery. The anesthesia helps numb nerves at the bladder neck 56, which can become irritated during surgery.

Additionally, the catheter 20 can utilize iontophoresis, electroporation, and/or phonophoresis to assist the transportation of the agent into the prostatic ducts. These non-pressure means of transportation also enhance drug penetration across the prostatic epithelium and into prostatic tissue. These methods may also increase cellular penetration of certain agents. Examples of these agents include DNA, RNA, etc. These non-pressure means of transportation may also make penetration into prostatic calculi possible. Iontophoresis, electroporation, and phonophoresis are discussed in more detail in United States Patent 5,419,763, the disclosure of which was incorporated by reference above. Additional information on iontophoresis can be found in United States Application Serial No. 07/705,731, which was filed on May 24, 1991; United States Application Serial No. 07/957,209, which was filed on October 6, 1992; and United States Patent 5,286,254, the disclosures of which are hereby incorporated by reference.

Figure 8 illustrates alternative embodiments in addition to those described in United States Patent 5,419,763. For example, the catheter 20 can include a sheath 74 that covers an electrode 76 and delivery ports 48. The sheath 74 can be tubular and fixed to the catheter body 32 with adhesive 78. The sheath 74 can be formed from a polymer matrix that absorbs fluid that passes through the delivery ports 48. Alternatively, the sheath 74 can be formed from a porous membrane. The pores can be either microporous (0.2-100 micron) or macroporous (100 micron-1 millimeter) depending on the density of the pores and manufacturing process. Specific materials that can be used to form the sheath 74 include PTFE Teflon; woven polymer filaments such as nylon, LDPE, polyurethane, or Kevlar; braided polymers; and extruded or perforated polymeric or elastic tubing.

The catheter body 32 can include a portion 80 that has a narrowed diameter, thereby defining a recess 82. One skilled in the art will realize that narrow portion 80 can correspond to intermediate portion 36. The electrode 76 is positioned within the recess 82. The sheath 74 extends over the recess 82 and forms a delivery chamber 84 that is in fluid communication with delivery ports 48. In use, the fluid fills delivery chamber 84 and is either absorbed in sheath 74 or passes through the pores defined in sheath 74, thereby forming a path between the electrode 76 and the patient's body that is capable of conducting an electric current.

Alternatively, the electrode 76 can be mounted on the proximal or distal portion 34 or 38 of the catheter body, which has a larger diameter. In this alternative embodiment, the electrode 76 is still positioned between the distal and proximal occlusion balloons 40 and 42. Additionally, if sheath 74 is absorbent, catheter body 32 may define only a single delivery port 48 positioned proximate to one of the sheath's 74 oppositely disposed ends 86 or 88.

The sheath 74 has several advantages. For example, the sheath 74 will prevent the electrode 76 from being placed in direct contact with tissue along the urethral wall. Additionally, the sheath 74 helps to distribute the current so that there is not a single point at which the current will pass from the electrode 76 to the tissue. As a result, hot spots are prevented, which might otherwise cause the tissue directly adjacent to the electrode 76 to burn.

While the invention has been described in conjunction with a specific embodiment thereof, it is evident that different alternatives, modifications, and variations will be apparent to those skilled in the art in view of the foregoing description. Accordingly, the invention is not limited to these embodiments or the use of elements having specific configurations and shapes as presented herein.

THE CLAIMED INVENTION IS:

1. An apparatus for delivering an agent to a treatment area of a patient, the apparatus comprising:

a catheter having first and second portions, the second portion being more elastic than the first portion; and

distal and proximal balloons operably connected to the catheter, the distal and proximal balloons being positioned so that at least part of the second portion is between the distal and proximal balloons.

2. The apparatus of claim 1 wherein the first portion has a first cross-sectional area and the second portion has a second cross-sectional area, the first cross-sectional area being greater than the second cross-sectional area.

3. The apparatus of claim 2 wherein the first cross-sectional area has a circular circumference and the second cross-sectional area has an oblong circumference.

4. The apparatus of claim 2 wherein the catheter defines a plurality of lumens, each lumen having a substantially uniform diameter.

5. The apparatus of claim 1 wherein the distal and proximal balloons are operably connected to the second portion of the catheter.

6. The apparatus of claim 1 wherein the proximal balloon is operably connected to the first portion of the catheter and the distal balloon is operably connected to the second portion of the catheter.

7. The apparatus of claim 1 wherein the catheter further includes a third portion, the third portion being less elastic than the second portion, the first and third portions being on oppositely disposed ends of the second portion, further wherein the proximal balloon is operatively connected to the first portion and the distal balloon is operatively connected to the third portion.

8. The apparatus of claim 1 wherein the patient has a prostatic urethra and a membranous urethra, further wherein the distance between the proximal and distal balloons is about the same as the combined length of the prostatic and membranous urethras.

9. The apparatus of claim 8 wherein the distance between the proximal and distal balloons is about 3 cm to about 7 cm.

10. The apparatus of claim 1 wherein the patient has a prostatic urethra, further wherein the distance between the proximal and distal balloons is about the same as the length of the prostatic urethra.

11. The apparatus of claim 8 wherein the distance between the proximal and distal balloons is about 3 cm to about 6 cm.

12. The apparatus of claim 1 wherein the catheter has first and second portions, the second portion slidably engaging the first portion, further wherein the proximal balloon is operably connected to the first portion and the distal balloon is operably connected to the second portion.

13. An apparatus for delivering fluid to a treatment area of a patient, the apparatus comprising:

a catheter having first, second, and third portions, the second portion being more elastic than and positioned between the first and third portions; a proximal balloon operably connected to the first portion; and

a distal occlusion balloon operably connected to the third portion;

wherein the first portion has a first cross-sectional area, the second portion has a second cross-sectional area, and the third portion has a third cross-sectional area, the first and third cross-sectional areas being greater than the second cross-sectional area.

14. A method of delivering an agent to the prostate gland of a patient having a urethra and a bladder, the method utilizing a catheter having proximal and distal balloons and an intermediate portion between the proximal and distal balloons, the method comprising the steps of:

inserting the catheter through the urethra so that the distal balloon is positioned at the neck of the bladder;

inflating the proximal and the distal balloons; and

providing axial tension along the intermediate portion of the catheter, the axial tension urging the proximal and distal balloons toward one another.

15. The method of claim 14 wherein the catheter has a proximal portion and at least a segment of the intermediate portion is elastic, further wherein the steps of inflating and providing axial tension comprising the steps of:

inflating the distal balloon;

pulling on the proximal portion of the catheter;

inflating the proximal balloon; and then

releasing the proximal portion of the catheter.

16. The method of claim 15 wherein the urethra has a bulbous urethra, the method comprising the additional step of positioning the proximal balloon in the bulbous urethra prior to inflation of the proximal balloon.

17. The method of claim 14 wherein the catheter has a proximal portion and at least a segment of the intermediate portion is elastic, further wherein the steps of inflating and providing axial tension comprising the steps of:

inflating the proximal and distal balloons;

pulling on the proximal portion of the catheter; and

securing the proximal portion of the catheter to the patient's body.

18. The method of claim 17 wherein the urethra includes a membranous urethra, the method comprising the additional step of positioning the proximal balloon in the membranous urethra.

19. The method of claim 18 wherein the step of pulling on the proximal portion of the catheter is performed after the step of inflating the distal balloon and before the step of inflating the proximal balloon.

20. The method of claim 14 wherein the step of providing axial tension is performed after the proximal and the distal balloons are inflated.

21. The method of claim 20 wherein the catheter comprises first and second portions, the second portion slidably engaging the first portion, further wherein the proximal balloon is operably connected to the first portion and the distal balloon is operably connected to the second portion, still further wherein the step of providing axial tension comprises the step of moving the second portion of the catheter relative to the first portion of the catheter so that the proximal and distal balloons are urged toward one another.

22. The method of claim 21 wherein the urethra includes a bulbous urethra, the method comprising the additional step of positioning the proximal balloon in the bulbous urethra.

23. The method of claim 21 wherein the urethra includes a membranous urethra, the method comprising the additional steps of:

positioning the proximal balloon in the membranous urethra; and

securing the proximal portion of the catheter to the patient's body

before the step of moving the second portion of the catheter relative to the first portion of the catheter.

24. A method of delivering an agent to the prostate gland of a patient having a urethra and a bladder, the method utilizing a catheter having proximal and distal balloons, a proximal portion, and an intermediate portion between the proximal and distal balloons, the method comprising the steps of:

inserting the catheter through the urethra so that the distal balloon is positioned at the neck of the bladder;

inflating the distal balloon;

pulling on the proximal portion of the catheter, thereby providing axial tension along the intermediate portion of the catheter;

inflating the proximal balloon; and

releasing the proximal portion of the catheter, so that the axial tension will urge the proximal and distal balloons toward one another.

25. The method of claim 24 wherein pulling on the proximal portion of the catheter positions the proximal balloon in the bulbous urethra.

26. A method of delivering an agent to the prostate gland of a patient having a urethra and a bladder, the method utilizing a catheter having proximal and distal balloons, a proximal portion, and an intermediate portion between the proximal and distal balloons, the method comprising the steps of:

inserting the catheter through the urethra so that the distal balloon is positioned at the neck of the bladder;

inflating the distal balloon so that it is sized to be anchored at the neck of the bladder;

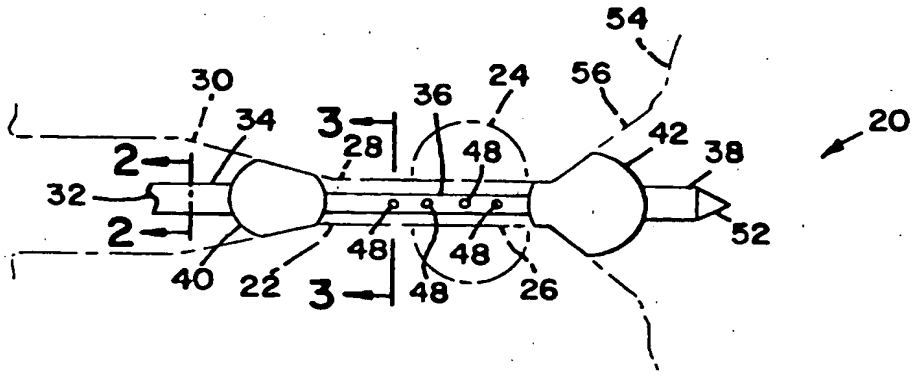
pulling on the proximal portion of the catheter, thereby providing axial tension along the intermediate portion of the catheter;

inflating the proximal balloon so that it is sized to be anchored against the wall of the bulbous urethra; and then

releasing the proximal portion of the catheter, so that the axial tension will urge the proximal and distal balloons toward one another.

27. The method of claim 26 wherein pulling on the proximal portion of the catheter positions the proximal balloon in the bulbous urethra.

FIG. 1



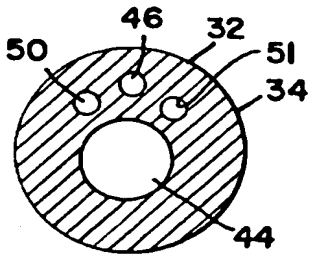


FIG. 2

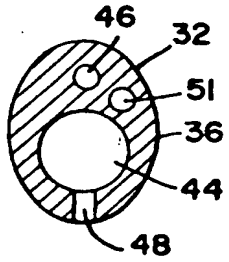
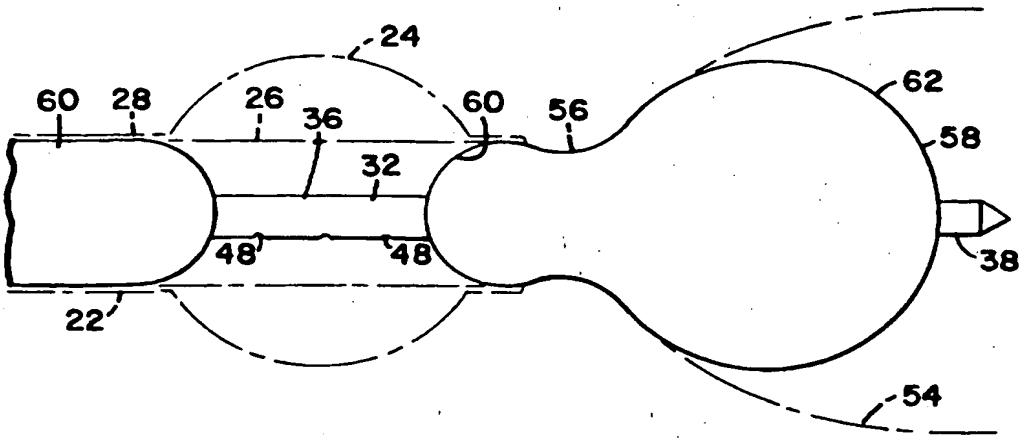


FIG. 3

FIG. 4



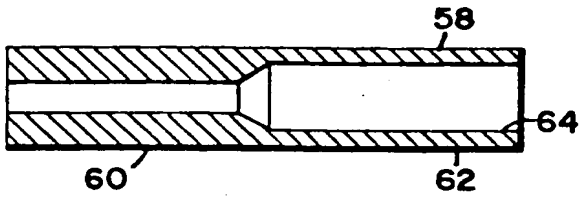
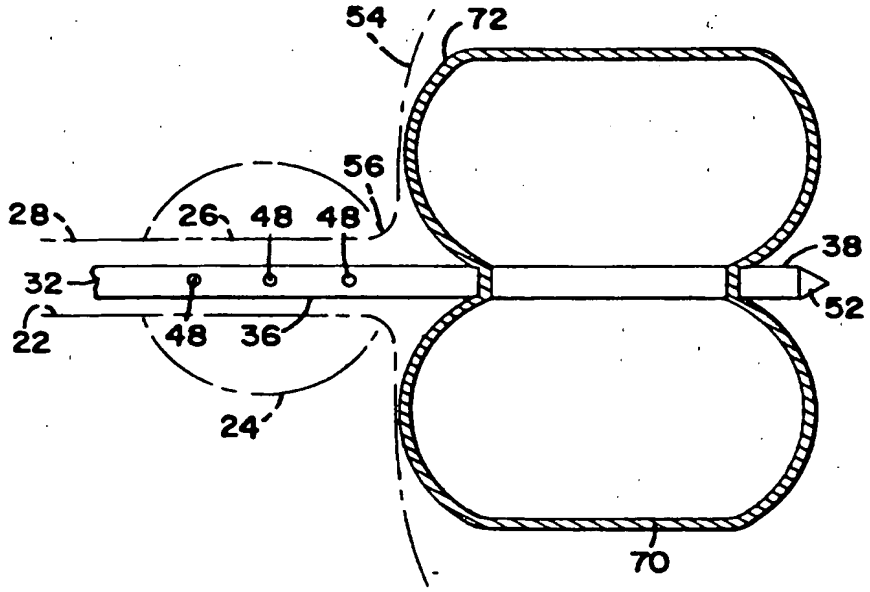


FIG. 5

FIG. 7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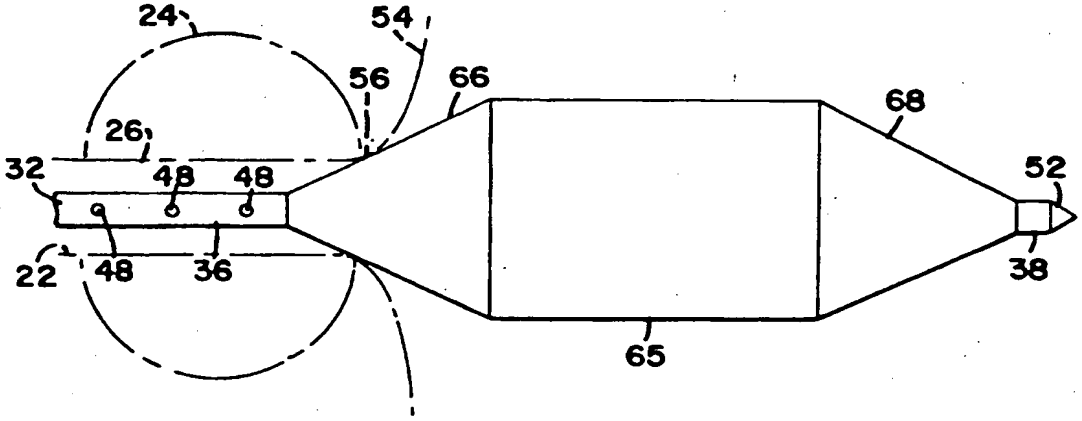
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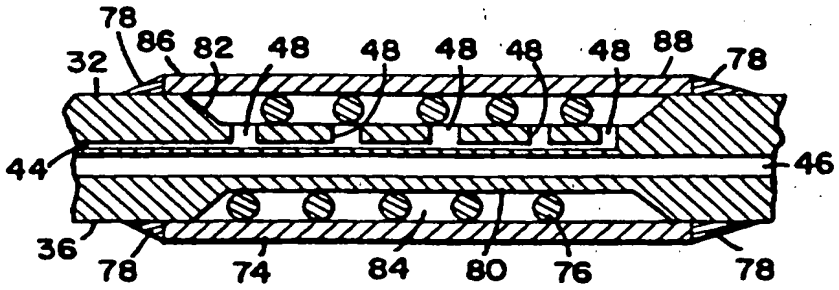
FIG. 6

FIG. 8



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/04614

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/10 A61J15/00 A61M1/10 A61B17/22 A61B1/12
A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61J A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 419 763 A (HILDEBRAND KEITH R) 30 May 1995 see column 2, line 33-52 see column 3, line 9-46 see column 5, line 18-50 see column 6, line 45-54 see column 8, line 14-50 see column 8, line 67 - column 9, line 5 see figure 4 ---	1,2,4-6, 8-12
X	US 5 478 309 A (SWEEZER WILLIAM P ET AL) 26 December 1995 see column 15, line 39-57 see figures 11,12 ---	1,2,6,12
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

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Date of the actual completion of the international search	Date of mailing of the international search report
27 June 1997	09.07.97
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Authorized officer Bichlmayer, K-P

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INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/US 97/04614

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 462 529 A (SIMPSON JOHN B ET AL) 31 October 1995 see column 2, line 43-67 see column 4, line 51 - column 5, line 50 see figure 1	1,2,6,12
X	EP 0 402 467 A (TERUMO CORP) 19 December 1990 see page 2 - page 4 see page 6 - page 9 see page 15; figures 4-6	1-3,6,12
A	US 5 104 377 A (LEVINE ANDY H) 14 April 1992 see column 5, line 19-63	1
A	EP 0 697 205 A (ROEWER NORBERT ;BRAUN MELSUNGEN AG (DE)) 21 February 1996 see column 1, line 52-59 see column 3, line 45-55 see column 4, line 59 - column 5, line 1 see figure 2	1
A	US 4 784 651 A (HICKEY DAVID S) 15 November 1988 see column 3, line 13-19 see figures 2-4	3

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 97/ 04614

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 13-27
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 13-27 relate to a method of treatment of the human or animal body by therapy (Rule 39(1)(iv)PCT).

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuatinn of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 97/04614

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